

CLINICAL SUMMARY



Prognostic value of EndoPredict test in patients with hormone receptor positive, human epidermal growth factor receptor 2-negative primary breast cancer screened for the randomized, double-blind, phase III UNIRAD trial

Penault-Llorca et al., ESMO Open 2024

Introduction

The prospective, randomized, double-blind UNIRAD trial explored the addition of everolimus to adjuvant endocrine therapy (ET) versus ET alone for high-risk, hormone receptor-positive, HER2-negative, (HR+/HER2-) early breast cancer.

EndoPredict (EPclin Risk Score) was used to classify patients into low- or high-risk. The study included a pre-planned exploratory sub-analysis to evaluate the prognostic added value of EndoPredict on outcomes of patients screened for the study.

Study design

Statistical analysis

- The sub-analysis was performed on all patients with an EPclin Risk Score who were screened for the trial.
- Evaluation of the endpoints disease-free survival (DFS) and distant metastasis-free survival (DMFS) were estimated from date of EndoPredict testing.
- Independent prognostic added value of EPclin Risk Score was tested in a multivariate Cox model after adjusting for grade, tumor size and nodal status.

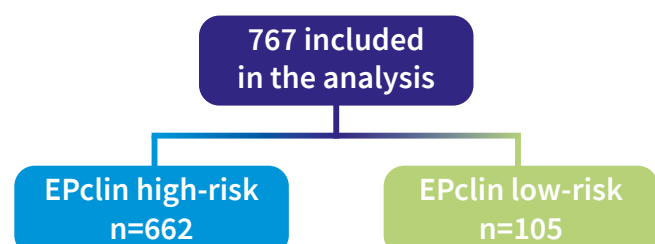
Treatment received

- Patients initiated ET 0-4 years before study entry.
- Most patients received adjuvant chemotherapy prior to study start.

Results

N=777 underwent EndoPredict screening* between 2015 and 2020:

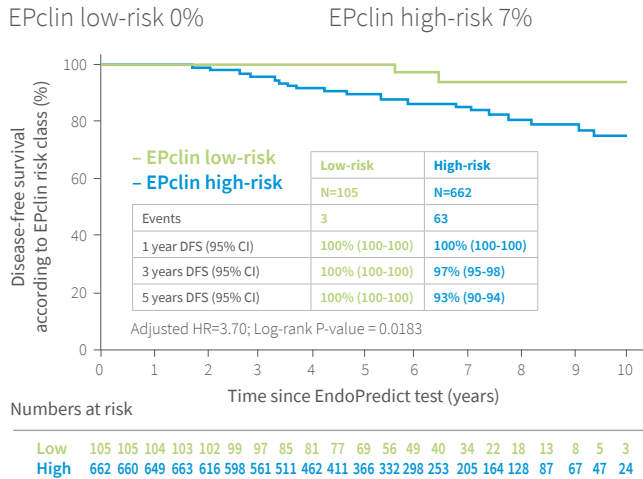
- Median age 54 (range 30 – 89), 35% premenopausal
- 97% N1-3, 1.8% N0
- 48% pT2, 9% pT3
- 60% Grade 2, 27% Grade 3
- Median follow-up 70 months



*EndoPredict was performed on treatment-naïve primary tumor from surgery or initial diagnostic biopsy. 10 patients excluded for incomplete test results or consent withdrawal.

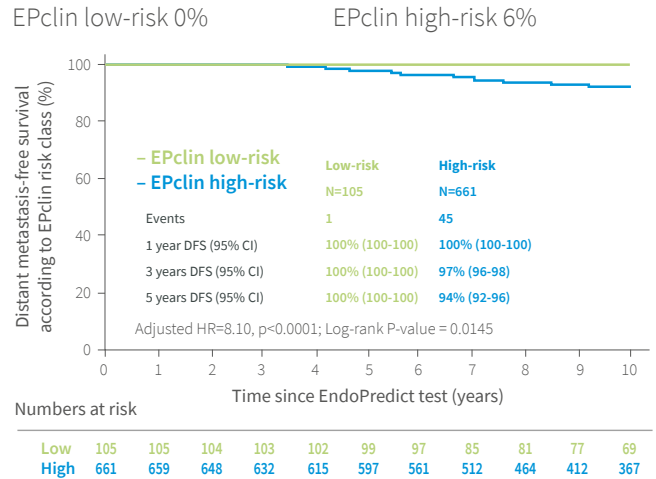
Primary endpoint: Disease-free survival

5-year relapse rate:



Secondary endpoint: Distant metastasis-free survival

5-year DMFS:



Uni- and multi-variate analysis

- EPclin Risk Score was the only independent prognostic parameter in a multivariate Cox model after adjusting for grade, tumor size and nodal status.
- Age and menopausal status were not significant in the univariate analysis.

	Class	Hazard ratio	CI 95%	P-value
EPclin Score		1.52	1.09-2.13	0.0141
Positive nodes	0-1	-	-	0.9800
	2	1.009	0.56-1.81	
	≥ 3	0.944	0.49-1.81	
Tumor Grade	Grade I	-	-	0.6582
	Grade II	1.31	0.45 - 3.79	
	Grade III	1.61	0.51 - 5.03	
Pathological size (longest axis)	<10 mm	-	-	0.2350
	10-20 mm	0.481	0.10 - 2.34	
	20-30 mm	1.061	0.24 - 4.64	
	30-50 mm	1.213	0.27 - 5.33	
	≥ 50 mm	1.362	0.31 - 5.99	

Conclusions

- The results confirm the value of the EPclin Risk Score as an independent prognostic parameter in node-positive ER+/HER2- early breast cancer patients receiving standard adjuvant treatment.
- EPclin Risk Score can identify low-risk patients who could be candidates for de-escalation studies, and very-high-risk patients who are candidates for optimum adjuvant treatment.

Bottom line

- This is the first prospective validation data of a second generation test in a randomized study with a remarkable lack of events in the low-risk group of patients.
- This analysis provides Level of Evidence 1A data, confirming EndoPredict's efficacy in evaluating node-positive early breast cancer.



Eurobio Scientific GmbH
Nattermannallee 1, Building S19
50829 Köln
Germany

info-INT@eurobio-scientific.de
www.eurobio-scientific.de



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